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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|--------------------------------|----------------------|--------------------------|------------------|
| 10/568,577 | 08/29/2006 | Hirokazu Kuwabara | Q93303 | 6508 |
| 65565 SUGHRUE-265 | 7590 02/24/200 5 550 | | EXAMINER | |
| | LVANIA AVE. NW | | DAVIS, ZINNA NORTHINGTON | |
| WASHINGTON, DC 20037-3213 | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 02/24/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | |
|---|---|--|--|--|--|
| | 10/568,577 | KUWABARA ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Zinna Northington Davis | 1625 | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | orrespondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D/ - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute. Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | |
| Responsive to communication(s) filed on <u>26 №</u> This action is FINAL . 2b) This Since this application is in condition for alloware closed in accordance with the practice under Expression in the practice of t | action is non-final. nce except for formal matters, pro | | | | |
| Disposition of Claims | | | | | |
| 4) ☐ Claim(s) 1-6 is/are pending in the application. 4a) Of the above claim(s) 2-5 is/are withdrawn 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1 and 6 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o Application Papers 9) ☐ The specification is objected to by the Examine | r election requirement. r. | -vaminar | | | |
| 10) The drawing(s) filed on is/are: a) accomplicated any objection to the Replacement drawing sheet(s) including the correct and the oath or declaration is objected to by the Explanation and the correct and the corre | drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 02/17/08. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | | |

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DETAILED ACTION

1. Claims 1-6 are pending.

- 2. At page 1 of the specification, the continuing data should be updated.
- 3. In the response filed November 26, 2008, Applicants have elected Group I, claims 1 and 6, without traverse. Applicants also identify the compound (I)-2 on page 42 as the preferred species.
- 4. Based upon the election of the compound (I)-2, the election of species requirement is withdrawn; however, the restriction requirement is maintained.
- 5. Applicants state the election is made without traverse, except it is submitted that claim 5 is not limited to a process of preparing a chemical compound of formula (IV), and thus it should be included in Group I.
- 6. It is the Examiner's position that claim 5 is not drawn to a compound of formula I. If the claim is drawn to a compound of formula I, this claim would be included in the invention of Group I.
 - The requirement is still deemed proper.
 - The requirement is therefore made FINAL.
- 7. Claims 2-5 are withdrawn from consideration. These claims have not been canceled.
- 8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

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a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

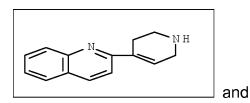
- 10. Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - A. What radicals are intended at the R position of the carbonyl radical (alone or in combination forms)? For instance, -C(O)-R represents carbonyl. Clarification is appreciated.
 - B. It is suggested that the phrase "and a salt" should be amended to read as "or a salt".
 - C. At claim 6, there is no antecedent basis for substituted amino?
- 11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 12. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Eli Lilly & Company (Reference N, cited by the Examiner).

The instantly claimed compounds are disclosed. At page 14, lines 1-3, see the named compound. The compounds are depicted below:

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- 13. The Information Disclosure Statement filed February 17, 2006 has been considered.
- 14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.
- 15. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communications.
- 16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zinna Northington Davis/ Zinna Northington Davis Primary Examiner Art Unit 1625